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Codman

MALIS® MODULE 1000™ Irrigation System

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ENGLISH

MALIS® MODULE 1000™ Irrigation System

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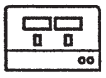
Classification

Equipment Function:	Irrigator
Type of protection against electrical shock:	Class I
Degree of protection against electrical shock:	Type BF
Supply Connection:	60 Volt-Amp 100–230 VAC 50–60 Hz
Mode of Operation:	Continuous with intermittent loadi 20 sec. on/40 sec. off
Protection against hazards of explosion:	Not suitable for use in the presenc of a flammable anesthetic mixture with air, oxygen, or nitrous oxide
Protection against ingress of liquids:	Drip-proof
Degree of Mobility:	Portable

Table of Symbols

	Primary (Mains) power on
	Primary (Mains) power off
	Alternating current
	Fuse
	Saline bag
	Forceps
	Attention, see instructions for use
	Type BF equipment—having an applied part with or without an intentional electrical path to the patient
	Electrosurgical generator connection receptacle
	Equipotentiality
	Alert
	Cut Irrigation
	Coag Irrigation
	Cut-Coag Irrigation Selector

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IMPORTANT INFORMATION
Please Read Before Use

MALIS MODULE 1000 Irrigation System

℞ Only

Instruction and Service Manual

IMPORTANT: Please read entire Instruction Manual before attempting to operate this unit.

Description

The MALIS MODULE 1000 Irrigation System (referred to as the module) is an irrigation control system for use with the MALIS CMC®-III Bipolar Electrosurgical Systems (catalog no. 80-1170, 80-1171, and 80-1172) and the SYNERGY® MALIS Precision System (catalog no. 80-1187). This system provides controlled flow of irrigating fluid across the tips of bipolar irrigating forceps. The rate of irrigation is operator adjustable.

Use the appropriate MALIS MODULE 1000 Interconnecting Cable to connect the module to your generator.

Indications

The MALIS MODULE 1000 Irrigation System is indicated for use with irrigating bipolar forceps with the CODMAN®/MALIS generators.

WARNINGS

Read the entire instruction manual before attempting to operate the module.

Electrical shock hazard:

- Do not attempt to bypass the grounding prong on the module by using an adapter. The module must be grounded properly to ensure operator and patient safely. Grounding reliability can be achieved only when connected to a receptacle marked “Hospital Only” or “Hospital Grade.”
- Do not remove the cover. Refer servicing by qualified service personnel.
- Disconnect the power cord to isolate the unit from the supply mains. Serious shock hazards are present inside this case even with the power switch off.
- Always replace the module’s fuse with the appropriate type and value fuse (see Technical Specifications).
- Do not modify the module in any way. Unauthorized modifications to the module can cause it to malfunction or fail in use.

When used in conjunction with an Electrosurgical Generator, do not operate the system near patient devices such as pacemakers, etc., that are sensitive to radio frequency interference.

Precautions

Use only the CODMAN MODULE 1000 Tubing Sets (catalog no. 80-9102, 80-9103, or 80-9104) with this unit.

Use only the CODMAN Floorstand (catalog no. 80-1147) with this unit.

Do not load the tubing set or connect the forceps cable before verifying operation to the module, as the unit can malfunction. See Set Up instructions.

Always check that the power cord and connecting cable are functioning properly before using in a surgical procedure to avoid unit failure.

Cleaning and Sterilization

Clean the module exterior surfaces monthly (or more frequently if necessary) with a damp cloth or sponge. Use alcohol or a mild cleaning solution to remove stains or adhesives that stick to the surface. DO NOT immerse the module in any solution. Subjecting the module to excessive moisture can damage the electronic components and nullify the warranty.

Never sterilize the module or power cord.

The irrigation tubing sets are sold sterile and are for single use only. Do not re-sterilize.

System Description

Controls, Indicators and Connections

FRONT PANEL

A. Irrigation Rate Display
This LED indicator numerically shows the flow setting.

B. Irrigation Rate Knob
The Irrigation Rate Knob adjusts the rate of irrigation. Turning the knob clockwise increases the irrigation rate and counterclockwise decreases the rate. The irrigation rate is indicated on the Irrigation Rate Display. When the irrigation rate is set to zero, the irrigation is disabled for that mode (Coagulation or Cut). Pushing in the Flow Rate Knob switches between the Coagulation Irrigation and Cut Irrigation display modes. When the Coagulation Irrigate Indicator is illuminated, the Flow Rate Knob controls the Coagulation rate of irrigation. When the Cut Irrigate Indicator is illuminated, the Flow Rate Knob controls the Cut rate of irrigation.

C. Coagulation and Cut Mode Irrigate Indicators
When the Coagulation Irrigate Indicator is illuminated, the Display indicates the Coagulation rate of irrigation. When the Cut Irrigate Indicator is illuminated, the Display indicates the Cut rate of irrigation. To change the display from one mode to the other, push in on the Irrigation Rate Knob.

FLOW RATE SETTINGS

Cut Irrigation Mode	Coag Irrigation Mode	Flow Rate
1	1	Slow Drip
2	2	Slow Drip
3	3	Slow Drip
4	4	Slow Drip
5	5	Slow Drip
6	6	Medium Drip
7	7	Medium Drip
8	8	Medium Drip
9	9	Medium Drip
10	10	Medium Drip
11	11	Medium Drip
12	12	Medium Drip
13	13	Medium Drip
14	14	Medium Drip
15	15	Medium Drip
16	16	Fast Drip
17	17	Fast Drip
18	18	Fast Drip
19	19	Stream
20	20	Stream

D. Alert Indicator
If the Alert Indicator is illuminated or flashing, an error condition has been detected by the unit. Return the unit for service.

REAR PANEL

E. Power Switch
This rocker switch controls the primary AC power to the module. When the module is ON the Irrigation Rate Display LEDs above the Irrigation Rate Knob illuminate.

F. Generator Connection Receptacle
Please refer to the instructions that accompany your cable to determine the correct method of connecting the cable to the module.

G. Equipotential Connector
This terminal is used to connect a potential equalization conductor to a busbar in rooms where potential equalization is required.

H. Power Receptacle
The power receptacle accepts the three-prong power cord plug and also contains the external fuses. (See Technical Specifications.)

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Instructions for Use

Set Up

The MALIS MODULE 1000 Irrigation System is for use with the MALIS CMC-III or SYNERGY Bipolar Electrosurgical Systems.

1. Mount the module on the CODMAN Floorstand (catalog no. 80-1147).

Note: For Current MALIS CMC-III Irrigation Module Users: The mounting bracket on the MODULE 1000 is on the left side of the unit whereas on the previous model it was on the right. Mount the MODULE 1000 to the floorstand in place of the previous unit, then turn the generator so that both units face the same direction.

2. Plug the MALIS MODULE 1000 Interconnecting Cable into the footpedal connection receptacle on the rear panel of the module. Please refer to the instructions that accompany your cable to determine the correct method of connecting the cable to the module. Support the module with one hand while inserting or removing the cable connector.

Note: The MALIS MODULE 1000 Interconnecting Cable connects the circuits of the module to the MALIS CMC-III and SYNERGY Bipolar Electrosurgical Systems, eliminating the need for a second footpedal.

Note: To avoid unintentional irrigation, be sure the power on the generator is switched to the ON position before the power switch on the irrigation module is switched to the ON position.

3. Plug the power cord into the power receptacle on the rear panel of the module and into an appropriately grounded 100–230 VAC 50/60 Hz power supply. The power receptacle provides an interface to cord/mains source and fuse replacement. A wide range of cords and plugs can be used for maximum flexibility in connecting to various mains sources.

WARNING: Do not attempt to bypass the grounding prong on the module by using an adapter. The module must be grounded properly to ensure operator and patient safety. Grounding reliability can be achieved only when connected to a receptacle marked “Hospital Only” or “Hospital Grade.”

4. Push the power switch on. The LED flow rate indicator above the flow rate knob will illuminate.

5. Turn the flow rate knob clockwise until the flow rate indicator reads “10.”

6. Open the module door and lift the pump hood.

7. Depress the footpedal (connected to the generator) and verify that it causes the pump roller to spin.

Note: Do not load the tubing set or connect the forceps cable before verifying operation of the module.

Loading the Irrigation Tubing Set

Use only the CODMAN MODULE 1000 Tubing Sets (catalog no. 80-9102, 80-9103, or 80-9104) with the unit. After verifying operation of the module (see Set Up), load the tubing set as follows:

1. Push the power switch of the module on.

2. Using sterile technique, remove the tubing set from the peel pouch.

3. Remove the protective cap from the irrigation tubing inlet spike. While holding the irrigation solution container vertically (with prepared stopper on top), push the spike into the center of the prepared stopper with a quick thrust. DO NOT TWIST.

4. Engage the irrigation tubing clamp.

5. Place the container, stopper face down, on the IV pole.

6. Open the module door and lift the pump hood.

7. Locate the silicone tubing located between the two plastic fittings.

8. Starting from the top, thread the tubing through the slot, around the rollers, and through the exit opening at the bottom of the pump head (Figure 1). The plastic fitting nearest the irrigation solution container should be at the top of the pump head and the fitting nearest the forceps should be at the base.

9. Connect the tubing set and forceps by pushing their connectors together.

10. To prime the system, release the irrigation tubing clamp. Prime the tubing set fully by removing as many air bubbles as possible before using. Verify flow in the system by observing irrigation through the forceps. When the tubing set is fully primed, close the pump hood to stop the fluid flow. Be careful not to pinch the silicone tubing when closing the pump hood (Figure 2).

Irrigation

1. After the tubing set has been loaded, depress the footpedal to activate irrigation. Release the footpedal to deactivate.

Note: To avoid unintentional irrigation, be sure the power on the generator is switched to the ON position before the power switch on the irrigation module is switched to the ON position.

2. Select the irrigation rate using the rate knob on the front panel of the module. With forceps attached, turn the knob clockwise to increase the irrigation rate and counterclockwise to decrease the irrigation rate.

3. When switched on, the module defaults to coagulation irrigation mode (Coagulation Irrigate Indicator is illuminated). In order to change to the cut irrigation mode, either push in the Irrigation Rate Knob or depress the cut footpedal. This will illuminate the Cut Irrigate Indicator and change the numeric display to the cut irrigation setting.

Note: The coagulation irrigation and cut irrigation settings can be set to different levels. For example, coagulation irrigation setting can equal 10 while the cut irrigation setting can equal 3.

4. To change back to the coagulation irrigation mode, push in the Irrigation Rate Knob or depress the coagulation footpedal. This will illuminate the Coagulation Irrigate Indicator and change the numeric display to the coagulation irrigation setting.

Troubleshooting Guide

Symptoms

1. Module does not operate (Irrigation Rate Display does not light)

Probable Cause	Correction
a. Module not plugged into power outlet	a. Plug in module
b. Blown fuse	b. Replace fuse
c. Loose wire at power cord plug	c. Check plug for wiring
d. No power at wall outlet	d. Check electrical service
e. Module defective	e. Return for repair
f. Alert LED is illuminated or blinking	f. Module diagnostic failure, return for repair

2. Irrigation fluid not controlled

Probable Cause	Correction
a. Tubing not primed	a. Prime tubing
b. Tubing not seated properly	b. Check tubing alignment in pump hea

3. No irrigation fluid flow

Probable Cause	Correction
a. Tubing pinched in pump head	a. Check tubing alignment in pump hea
b. Tubing clamp engaged	b. Release tubing clamp

4. Irrigates without pressing footpedal

Probable Cause	Correction
a. CMC-III generator turned off	a. Turn on CMC-III generator before turning on irrigator

Note: Only qualified service personnel should attempt to repair the module

Service and Repair

For service and repair, contact Codman Repair Customer Service at 1-800-343-5969.

End of Useful Life

Dispose of the equipment in accordance with local ordinances.

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Warranty

Codman & Shurtleff, Inc., warrants that this medical device is free from defects in both materials and workmanship for one full year from date of purchase. Only the CODMAN MODULE 1000 Tubing Sets are approved for use with the module. Use of any other tubing set nullifies this warranty. **Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.**

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™ MODULE 1000 is a trademark of Codman & Shurtleff, Inc.

APPENDIX A: Service Manual

Field Maintenance and Repair

This section contains the necessary information to allow a qualified service technician to perform maintenance and repair in the field. Equipment under warranty should be returned to Codman & Shurtleff, Inc. It will be repaired or replaced without charge to the purchaser.

Technical Specifications

Supply Voltage

60 VA at 100–230 ±10% VAC

Supply Frequency

50/60 Hz

Supply Current

0.60 A

Fuses

5 x 20 mm, T1A, 250 V (slow blow)

Environmental:	Operational:	Transport & Storage:
Temperature	10°C to 45°C	5°C to 55°C
Relative Humidity (noncondensing)	30% to 70%	0% to 90%
Atmospheric Pressure	700 hPa to 1060 hPa	500 hPa to 1060 hPa

Safety Information

The MALIS MODULE 1000 Irrigation System complies with the requirements of IEC 60601-1.

Maintenance

A change in the flow characteristics of the module may indicate the need to replace the rollers located in the pump head. Consult the appropriate facility for this possible repair.

No other preventive maintenance is required.

Theory of Operation

The MALIS MODULE 1000 Irrigation System operates by use of a peristaltic pump in conjunction with the silicone insert portion of the MALIS MODULE 1000 Tubing Set. The tubing set is connected to an irrigation solution container. The fluid flow is propelled by the peristaltic pump. The irrigation rate is operator controlled by the knob located on the front panel.

Controller Board

The controller board contains the microcontroller, U2, and software that operate the module. The microcontroller communicates via the I2C bus with the display driver, U1, to set the numeric displays and indicator LEDs. Rotating the rotary switch, S1, increases or decreases the irrigator setting. Pushing in the rotary switch switches between cut and coag irrigation mode The microcontroller interfaces to the stepper motor controller, U3, via sever signals. A LO to HI transition on the STEP_CLK signal causes the motor controller to step or rotate the motor and peristaltic pump.

Inputs to the controller board include the footpedal/generator interface (connecting cable). Depressing the footswitch causes the module to begin pumping action. The rate at which the pumping action occurs is controlled by the microcontroller and software.

Power Supply Board

The power supply board consists of an off-line switching power supply to produce regulated low voltage supplies. The mains voltage connects to an EMI filter and bridge rectifier to produce unregulated DC voltage. The switching controller, U1, and transformer, T1, regulate the DC voltage to a lower level, which is fed into a linear regulator, U2. The linear regulator U2, produces a regulated 27 volt supply that is used to drive the motor controller. The 27 volts is fed into another linear regulator, U3, to produce a 5 volt supply that powers the controller board circuits.